Document Development and Control Procedure

Document Number: 04.03.004.001

Effective Date: 9/30/19

REVISION HISTORY/PERIODIC REVIEW TABLE

Revision Number	Revision/Review Date	Description of Revision/Review Comments
0	8/16/19	Development of a new procedure that provides guidelines on development and control Institutional Assurance & Integrity implementing documents.

TABLE OF CONTENTS

1.0 PURPOSE & SCOPE

This standard operating procedure (SOP) is an internal Office of Institutional Assurance & Integrity (A&I) document that defines the guidelines to ensure that A&I's key processes are documented and controlled in a manner that ensures:

1. consistency across A&I's implementing documents,
2. current versions of documents are being used, and
3. reviews are performed of initial, modified and current documents to ensure that they are complete, correct, accurate, relevant and dispositioned appropriately.

Applicable documents include A&I system, program and process descriptions, manuals, and procedures. In addition to the guidelines outlined in this SOP, A&I Institutional-level documents such as policies, system/program descriptions, etc. will adhere to the Institutional Requirements Management Process (Document Number 04.04.001.003). A&I implementing documents that are identified as contract deliverables will adhere to the Contract Deliverables Process (Document Number 04.04.001.104). See Appendix A. for Institutional- and organizational-level documents.

Records generated by execution of this SOP include signed documents and retired documents. Records are maintained in accordance with the Lab's Archive and Records Management Policy (Document Number 10.03.001.000).

2.0 BASELINE & REFERENCED REQUIREMENTS

2.1 Baseline References

- DOE O 414.1D, Quality Assurance
- LBNL/PUB-3111, Quality Assurance Program Description (QAPD)

2.2 Referenced Requirements

- Contract Deliverables Process (Document Number 04.04.001.104)
- Requirements Management Process (Document Number 04.04.001.003)
- Archive and Records Management Policy (Document Number 10.03.001.000)

3.0 ROLES & RESPONSIBILITIES

Role	Responsibilities
A&I Director	● Establish and manage a system and procedures for managing and controlling A&I documents throughout the document lifecycle ● Participate in the document review and approval process.
A&I Program/Process Owner	● Design, develop and maintain new and/or revisions to Institutional or internal documents in accordance with this procedure. ● Obtain stakeholder review/approval and feedback for new and/or major revisions to Institutional or internal documents, as necessary. ● Perform periodic reviews of program and/or process documentation to ensure the content is current, and modify documents, as necessary ● Ensure documents that satisfy contract deliverables are

Role	Responsibilities
	completed and submitted to the Requirements Management Program Manager by the contract deliverable due date. ● Ensure that the final signed document (i.e., quality record) is uploaded to the appropriate A&I Google Drive Shared Folder.
Reviewer	● Participate in the document review and approval process.
Requirements Management Program Manager	● Update the contract deliverable list, if appropriate, in accordance with the Contract Deliverables Process.

4.0 IMPLEMENTATION

4.1 Document Lifecycle

Documents exist within a defined lifecycle, which include the following primary steps.

- Write documents
- Review draft documents
- Approve draft documents
- Distribute documents
- Access and use documents
- Periodic review documents
- Revise documents, if necessary
- Retire documents
- Archive documents

4.2 Document Identification

Documents must be uniquely identified with a title and document number for control purposes, which should not be used to identify another document. Document identification for both Institutional- and organizational-level documents will follow the Institutional Requirements Management document numbering convention.

Document numbers are comprised of four fields separated by periods, and a version suffix separated by a hyphen: XX.YY.ZZZ.AAA, where:

- XX is the two-digit number reflecting the RPM Section
- YY is the two-digit number reflecting the Policy Area
- ZZZ is the three-digit number reflecting the policy number
- AAA is a three digit number reflecting the support or implementing document number, and

Documents already assigned an LBNL Publication document number (LBNL-PUB) will retain those numbers.

RPM Section 04 (XX) has been assigned to Contractor Performance Management. Within this RPM Section, there are three Policy Areas (YY) with various policy numbers (ZZZ) associated with them, which are

1. Contractor Assurance (02),
    a. 001 – Contractor Assurance System
    b. 002 – Assessment

c. 003 – Issues Management
d. 004 – Price Anderson Amendment Act (PAAA)

2. Quality Assurance (03), and
    a. 001 – Quality Assurance
3. Requirements Management (04)
    a. 001 – Requirements Management

A document that pertains to Contractor Assurance will start with the RPM Section number, followed by the Policy Area, then the Policy number and then number that denotes the implementing document that supports the specific policy. For example, the Issues Management Program Manual is numbered 04.02.003.000, the last three numbers of which reflect the first in a series of Manuals/Procedures.

Institutional training courses such as Issues Management Training, Suspect/Counterfeit Items Awareness training, are comprised of a Berkeley Lab Institute (BLI) prefix and a numerical suffix: BLIXXXX where:

- XXXX is the four-digit number reflecting the sequential number of the training course numbers.

4.3 Document Review

4.3.1 Initial and Revised Documents

Documents must be reviewed for completeness, correctness and accuracy prior to issuance and release commensurate with the type of modification. New documents and major changes to an existing document should be reviewed by appropriate stakeholders to obtain relevant input and their feedback should be addressed prior to approving and/or signing it for issuance and release.

Minor changes to an existing document do not need to be reviewed by the original stakeholders prior to approving and/or signing it for issuance and release.

If document signatures are necessary, they may be obtained via hard copy or electronic signature. Electronic signatures should be obtained through Lab approved electronic signature applications such as HelloSign and Adobe Acrobat.

4.3.2 Periodic Review of Existing Documents

Documents should be reviewed and revised, as necessary when there is a change in requirements, policies, programs, processes, etc. Documents should be reviewed by the Program Manager or Process Owner on a periodic basis to ensure that they are still complete, correct, accurate and relevant, based on the Requirements Management Process requirements for Institutional documents or the A&I protocol determined at document creation.

Periodic reviews must be documented in the Revision History/Periodic Review table. Periodic reviews that require modification will follow the appropriate sections of this SOP.

During periodic review or any interim review, a controlled document may be identified for retirement. Documents that are no longer considered relevant should be removed from the appropriate websites and should be marked as “Retired” to prevent use. Documents should also be moved to the A&I Archive folder on the A&I Google Shared Drive.

Documents that have been superceded by a different document should be removed from the appropriate websites and should be marked as “Superceded by X document” to ensure the most current and relevant document is being used.

4.4 Document Issuance and Release

Final approved and/or issued/released implementing documents will be in electronic Adobe Acrobat (.pdf) file format, and must be uploaded to the A&I Activities Google Shared Drive and appropriate A&I webpage to ensure that the record (the final approved and signed document) is retained in a central repository and easily retrievable by those who need to implement and execute to the document.

If signatures were obtained via hard copy, they must be scanned and included in the documents’ electronic file format. If signatures were not obtained or needed, approval must be documented via email or other mechanism.

Each initial document will be assigned a revision number, starting with “1”, and the next sequential number will be used for each subsequent revision. The revision number will be identified on the initial and modified documents. Upon release of a new version of a document, the previous version is retired.

New and modified documents should follow the identification convention below:

- Document Title
- Document Number
- Revision Number
- Effective Date (i.e. date of issue)

4.5 Document Format

Each document follows a standardized format, which includes the elements outlined below, to ensure consistency across A&I documents.

1. Title Page
2. Signature Page, as necessary, for Institutional-level documents that are Contract Deliverables that are required to be approved.
3. Revision History/Periodic Review Page
4. Table of Contents
5. Purpose and Scope
6. Baseline and Referenced Requirements
7. Roles and Responsibilities
8. Implementation (e.g., Process Steps)
9. Appendices, as necessary:
    a. Definitions
    b. Template(s)
    c. Additional information as needed (e.g., process flow charts, additional guidance, etc.)
10. Each page, with the exception of the Title Page, should include a header that states the Document Title, Document Number, Effective Date, and Page number (i.e. Page X of Y).

Appendix C includes detailed guidance on the format of implementing documents.

Appendix A – A&I Institutional and Organizational Documents

Institutional	Documents
Policies	• LBNL/Pub-201, Requirements and Policies Manual • Doc. No. 04.02.001.000, Contractor Assurance Policy • Doc. No. 04.02.004.000, Price Anderson Amendment Act (PAAA) Compliance Policy • Doc. No. 04.03.001.000, Quality Assurance Policy • Doc. No. 04.04.001.000, Requirements Management Policy
System and Program Descriptions	• LBNL/Pub – 5524, Contractor Assurance System Description (CASD) • LBNL/Pub – 3111, Quality Assurance Program Description (QAPD)
Program Manuals	• BSO Directives Process Manual • Doc. No. 04.02.004.001, Price Anderson Amendment Act (PAAA) Compliance Program Manual • LBNL/Pub-5519, Issues Management Program Manual
Process Descriptions	• Institutional Risk Management Framework Description • Doc. No. 04.02.002.000, Institutional Assessment Process Description
Schedules	• Integrated Assessment Schedule
Standard Operating Procedures	• Doc. No. 04.04.001.105, Graded approach for Requirements and Documents • Doc. No. 10.06.001.101, Developing, Reviewing, Approving Institutional Non-Policy Documents • Doc. No. 10.06.001.203, Policy Approval Form • Doc. No. 04.04.001.000, Requirements Management Governance • Doc. No. 04.04.001.004, Requirements management Process • Doc. No. 04.04.001.004, Requirements Management Database Requirements Specification • Requirements Management Committee (RMC) Charter • Doc. No. 04.04.001.106Proceessing of Approved Contract 31 Changes • Doc. No. 04.04.001.104, Contract Deliverables Management • Doc. No. 04.04.001.101, Analyzing Requirements, Determining Significance Rating from Impact and Risk Analysis • Doc. No. 04.04.001.102, Developing, Reviewing, Approving an Implementation Plan • Doc. No. 04.04.001.107, Initiating a Change to a Contract 31 Requirement • Policy Change Request • Doc. No. 04.04.001.201, Analyzing Requirements Form • Doc. No. 04.04.001.202, Implementation Plan Form • Doc. No. 04.04.001.206, Significance Rating Form • Doc. No. 04.04.001.208, Record of Decision Form • Doc. No. 10.06.001.001, Managing Institutional Documents Process • Doc. No. 10.06.001.101, Developing, Reviewing, Approving, Institutional Non-Policy Documents • Doc. No. 10.06.001.102, Developing, Reviewing, Approving, Institutional Policy Documents • Doc. No. 10.06.001.103, Storing, Retrieving, Archiving Institutional Documents • Doc. No. 10.06.001.104, Updating the RPM • Doc. No. 04.04.001.300, Processes for Pre-Adoption of LBNL Requirements • Doc. No. 04.04.001.301, Impact Analysis for Proposed Changes to C31

Institutional	Documents
	• Doc. No. 04.04.001.201, Analyzing Requirements Form • Doc. No. 04.04.001.302, BSO Pre-Contract31 Impact Analysis Worksheet • Doc. No. 04.04.001.303, Rev/Com Procedure for DOE Directives • Doc. No. 10.01.003.003, Safety Software Quality Assurance (SSQA) • Doc. No. 04.03.006.001, Safety Software Evaluation Form • Protocol for Handling Suspect or Counterfeit Items
Specification	• Institutional QA Specification for Subcontracts/Master Task Agreements for Capital Projects
Guidelines	• Principles for Conducting Incident/Event Analyses at LBNL • Guidelines for Accepting Sampling for Inspection
Training Courses	• BLI2005 Document Control 101 • BLI2007 Suspect/ Counterfeit Items Awareness • BLI2010 Corrective Action Development Training • BLI2011 LBNL Five-Whys Casual Analysis • BLI2012 Assessment Training • BLI2015 Barrier Causal Analysis • BLI2017 HPI Culpability Analysis • BLI 2018 CATS Tutorial • BLI 2028 Apparent Cause Analysis
Templates	• Apparent Cause Analysis Report • Investigation and Root Cause Analysis Charter Letter • Root Cause Analysis Report • Issue/Incident Summary for Factual Accuracy Review Example • Corrective Action Plan (CAP) • SMART Analysis Worksheet • CAP Development Charter Letter • Effectiveness Review Analysis • Effectiveness Review Charter • Effectiveness Review Methodology • Effectiveness Review Report • Extent of Condition/Cause (EOC) Report • Lessons Learned/Best Practices Briefing • Lessons Learned Event Debrief
Databases & User Support	• Risk Wizard • Corrective Action Tracking System (CATS) • OIA-OCA-0001, CATS Database User Manual • Lessons Learned/ Best Practices database
Organizational	**Documents**
A&I Standard Operating Procedures	• Doc. No. 04.03.004.001, Document Development and Control Procedure
A&I Work Instructions	

Appendix B - Definitions

Term	Definition
Controlled Document	A document that is reviewed and approved prior to use, version controlled, and has a life cycle.
Document	Written, visual, audio-video-recorded information stored in the form of hard copy, film, magnetic tape, electronic data, or in an on-line, web-based format.
Document Control	The process that provides for document adequacy review, approval for release by authorized personnel and distribution for use at the prescribed work locations.
Major Change	A change to the document that significantly impacts the document such as the system, program or process manager/owner; organizational changes; the purpose or scope; roles and responsibilities; performance steps.
Minor Change	A change to the document that does not significantly impact the document such as spelling, grammar, font sizes or types, or clarification of information.
Record	A completed record or any authenticated portion of a record that provides objective evidence of the quality of items or activities.
Retired	A document is retired when it is no longer relevant or needed, or a new revision of the document has been approved and issued/released.
Superceded	A document is superceded when an existing document is integrated into new or other existing document.

Appendix C - Implementing Document Template Guidelines

1. Title Page
   State the title of the document, including the document number, revision, and effective date. This information should be center justified.

2. Signature Page, as necessary
   If signatures are needed on a document, create a signature block that includes the approvers' printed name, title, organization, and a space for the approver to sign as well as a date block for the approver to identify the date the document was signed.

3. Revision History/Periodic Review Page
   This page contains the Revision History and Periodic Review table. For revisions, identify the sequential revision number of the revision, the date of revision and a brief summary of the changes made. For periodic reviews, N/A the "revision number" field, identify the date of the periodic review and provide a short description of the review. For example, if the periodic revision did not result in a modification to the document, state "No revision needed".

4. Table of Contents
   Include a Table of Contents that identifies the main sections of the document and the sections' correlating page numbers.

5. Purpose and Scope
   State the purpose and scope of the document, and to whom/what it applies. For example, what is the goal or objective of the document and what organizations, staff or activities does it apply to?. The goal or objective should include the "value proposition" of the document.

6. Baseline and Referenced Requirements
   Identify the baseline requirements, the higher tier requirements, that the document satisfies. Identify the referenced requirements, as applicable, that are referenced throughout the document that the reader can read to obtain additional information.

7. Roles and Responsibilities
   Identify the various roles/functions that execution of the document will require interface or integration with and state the high level responsibilities of each of these roles/functions as they pertain to execution of the document.

8. Performance
   State the performance steps/requirements and considerations that the people who will fulfill the roles/functions of the document can correctly execute the steps.

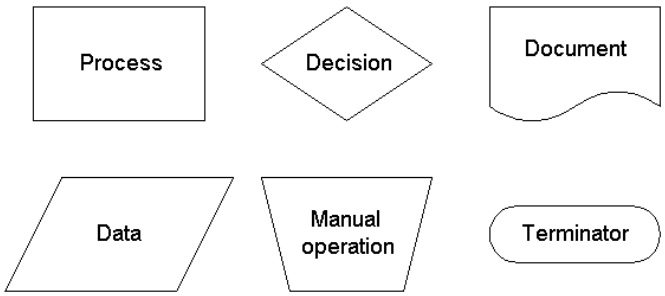
9. Appendices, as necessary:
   a. Definitions
      Include a definition table for any terminology that is not self-explanatory that states the term and the specific definition or meaning so that the reader has a common understanding of the terminology used for the particular system, process, activity, etc. described in the document.

   b. Template(s)
      Include any template (e.g., report format template, plan format template, etc.) that will be used to guide or instruct the reader of this document on how to execute the document.

c. Additional information as needed (e.g., process flowcharts, additional guidance, etc.)
Include other pertinent information that provides the reader with context and/or additional information to help improve understanding and execution of system, process, activity, etc. described in the document.

1. Process Flowchart Guidance
Process flowcharts can be used to visually show an end-to-end business process or portion thereof or the sequence of operations to be performed and should be easy to follow and understand by the viewer. Some general principles include:
   a. Use consistent design elements. Shapes, lines and texts within a flow chart should be consistent. Using consistency eliminates unnecessary distraction and makes the data flow or workflow very easy to follow.

      i. General shapes include:



      ii. Line types:
      An arrow from one process step to the next is often called a "Connector", a "Flow Line", or simply an "Arrow and show the direction of the process flow.
   b. Keep everything on one page. Try to make the flowchart fit on a single page and ensure the text remains readable. When a diagram becomes too large to fit on a page, it's advisable to divide it into multiple charts and connect them with hyperlinks.
   c. Flow data from left to right to make the information easier to read and comprehend. When needed, the data can be flowed in multiple left-to-right rows or top to bottom.
   d. For decision steps, use a “Decision” symbol (diamond), which will minimize the amount of lines coming to or from one shape to another.
   e. Place return lines under the flow diagram. People naturally read text from the top of the page down, it is logical that return lines should be placed under the flowchart rather than above. If two return lines are needed, they should not overlap.

Appendix D - Document Lifecycle